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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|------------------------|---------------------|------------------|
| 10/666,846  | 09/18/2003  | Robert Justice Shartle | LIFE-072CON6        | 5766             |
| 24353   | 7590        | 10/31/2005             | EXAMINER            |                  |
| BOZICEVIC, FIELD & FRANCIS LLP<br>1900 UNIVERSITY AVENUE<br>SUITE 200<br>EAST PALO ALTO, CA 94303 |             |                        | ALEXANDER, LYLE     |                  |
|   |             |                        | ART UNIT            | PAPER NUMBER     |
|   |             |                        | 1743                |                  |

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/666,846 | <b>Applicant(s)</b><br>SHARTLE ET AL. |  |
|                              | <b>Examiner</b><br>Lyle A. Alexander | <b>Art Unit</b><br>1743               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-45 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-39 and 41-45 is/are rejected.
- 7) ☒ Claim(s) 40 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/20/03; 12/19/03; 1/20/04; 3/23/05; 6/9/05.</u>                         | 6) <input type="checkbox"/> Other: ____.                                    |

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-39 and 41-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10; 10-21; 1-19 of U.S. Patent No. 6,908,593; 6,521,182; 6,261,519 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because all are directed to a fluidic device having a bladder, stop junction and bypass channel.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 22-39 and 41-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-36; 1-21; 1-21; 1-21 of copending Application No. 10/330,790; 10/330,456; 10/121,425; 10/121,636 respectively. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because all are directed to a fluidic device having a bladder, stop junction and bypass channel.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Objections***

Claim 40 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to parent claims only in the alternative. See MPEP § 608.01(n). Accordingly, the claim 40 has not been further treated on the merits.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 22-37 and 41-45 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Naka et al. (USP 6,001,307 or 6,180,062) or EP 0803288 (also Naka et al.).

The Naka et al. references teach a device in figure 21 a fluidic diagnostic device having multiple layer with the appropriate cut outs to a sample application port(4a), a first measurement area(3a), a first channel that traverses the length of the device, a compressible bladder(1) and a stop junction(3d) that prevents the sample from flowing into the bladder. The instant claim language is open and does not exclude the presence of additional measurement areas (e.g. 3b,3c) or the presence of a reagent in the stop junction(3d).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naka et al. (USP 6,001,307 or 6,180,062) or EP 0803288 (also Naka et al.).

The Naka et al. references teach a device in figure 21 a fluidic diagnostic device having multiple layer with the appropriate cut outs to a sample application port(4a), a first measurement area(3a), a first channel that traverses the length of the device, a compressible bladder(1) and a stop junction(3d) that prevents the sample from flowing into the bladder. The instant claim language is open and does not exclude the presence of additional measurement areas (e.g. 3b,3c) or the presence of a reagent in the stop junction(3d).

The Naka et al. references are silent to the claimed use of a polysulfone anisotropic filter.

Polysulfone anisotropic filters are notoriously well known in the art. These filters are used to rupture red blood cells, remove the subsequent cellular debris and permit analysis of the hemoglobin. These filters are advantageous because it eliminates the

need for a technician to denature the cells and permits the user to perform analysis directly on whole blood that is easily obtained from a prick.

It would have been within the skill of the art to modify either Naka et al. (USP 6,001,307 or 6,180,062) or EP 0803288 and use a polysulfone filter to gain the above advantages.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander  
Primary Examiner  
Art Unit 1743

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